IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

NMT MEDICAL, INC.,

Plaintiff,

v.

AGA MEDICAL CORPORATION,

Defendant.

Civil Action No. 04 12565 NG

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

NATURE OF ACTION

This is an action under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,108,420.

THE PARTIES

1. Plaintiff NMT Medical, Inc. ("NMT") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business in Boston, Massachusetts.

2. Defendant AGA Medical Corporation ("AGA"), is a Minnesota corporation, having its principal place of business in Golden Valley, Minnesota.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under Title 35 of the United States Code. Accordingly, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1338(a).

4. Venue is proper in this jurisdiction pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and/or 1400(b).

ACTS GIVING RISE TO THE COMPLAINT

5. Plaintiff NMT is the exclusive worldwide licensee of the right to make, use, and sell products embodying and/or manufactured according to the methods of United States Patent No. 5,108,420 (the "420 patent"), entitled "Aperture Occlusion Device." A complete and true copy of the '420 patent is attached as Exhibit A.

6. On December 10, 1998, NMT commenced litigation against AGA in this Court, alleging infringement of the '420 Patent. That litigation was captioned Nitinol Medical Technologies, Inc. v. AGA Medical Corp., 98-cv-12506-NG.

7. During the course of the parties' prior litigation, it became clear that two pieces of purported prior art were not before the Patent and Trademark Office ("PTO") when the '420 patent originally was prosecuted.

8. On April 25, 2001, the Court granted NMT's motion to stay the proceedings in the parties' original litigation pending reexamination of the '420 patent by the PTO.

9. Thereafter, on June 25, 2001, the inventor of the '420 patent voluntarily submitted the '420 patent to the PRO for reexamination in light of the purported prior art.

10. The Court held periodic status conferences during the following sixteen months. After each conference, the Court continued its order staying the proceedings. At a status conference on October 31, 2002, the Court indicated that it would consider dismissing the parties' original litigation without prejudice if the PTO did not issue a decision on the reexamination proceeding by the end of 2002.

11. On February 5, 2003, the PTO examiner conducting the reexamination rejected all of the claims of the '420 patent. NMT timely sought review of the PTO examiner's determination before the Board of Patent Appeals and Interferences.

12. On September 30, 2003, by letter to the Court, AGA requested that the ongoing stay of the parties' original litigation be converted into a dismissal without prejudice.

13. On December 2, 2003, while the PTO appeal was pending, the Court dismissed the parties' original litigation, without prejudice to NMT's right to refile the case in this Court depending upon the outcome of the PTO reexamination proceedings.

14. On August 19, 2004, the Board of Patent Appeals and Interferences reversed the PTO examiner's initial determination and found that the two pieces of purported prior art did not invalidate the claims of the '420 patent. The PTO Board remanded the '420 patent to the PTO examiner for proceedings consistent with the Board's decision.

15. On October 13, 2004, AGA brought a complaint against NMT in the District of Minnesota for a declaratory judgment regarding the issues of infringement and validity with respect to the '420 patent. AGA's Minnesota Complaint raises the same claims and defenses with regard to the '420 patent that were before this Court in the parties' original litigation.

COUNT I: INFRINGEMENT

16. NMT restates Paragraphs 1 – 15 of this Complaint.

17. AGA manufactures, offers for sale, or sells medical devices which infringe one or more of the claims of the '420 patent.

18. On information and belief, AGA's acts of infringement are willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, NMT requests that judgment be entered in its favor and that it be granted the following relief:

1. A judgment that AGA has infringed the '420 patent, and that such infringement has been willful;

2. A permanent injunction restraining AGA, its officers, agents, servants, and employees, and those acting in concert with it, from infringing the '420 patent.

3. An award of damages sufficient to compensate NMT for the infringement complained of herein;

4. An award of enhanced damages in the amount of three times the damages found or assessed, attorneys' fees, disbursements, and costs of suit; and

5. Such other and further relief as the Court deems just and proper.

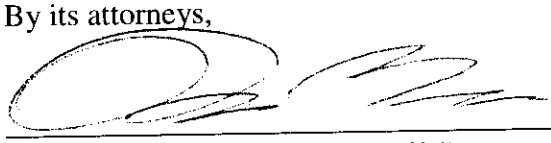
JURY TRIAL DEMAND

PLAINTIFFS HEREBY DEMAND TRIAL BY JURY.

Dated: December 7, 2004.

NMT MEDICAL, INC.

By its attorneys,



Dominic E. Massa (BBO #564694)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

1. Title of case (name of first party on each side only) NMT Medical, Inc. v. AGA Medical Corp.

2. Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).

☐	I.	160, 410, 470, R.23, REGARDLESS OF NATURE OF SUIT.	
☑	II.	195, 368, 400, 440, 441-444, 540, 550, 555, 625, 710, 720, 730, 740, 790, 791, 820*, 830*, 840*, 850, 890, 892-894, 895, 950.	*Also complete AO 120 or AO 121 for patent, trademark or copyright cases
☐	III.	110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.	
☐	IV.	220, 422, 423, 430, 460, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.	
☐	V.	150, 152, 153.	

04 12565 NG

3. Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.

NMT Medical, Inc. v. AGA Medical Corp., 98-cv-12506-NG

4. Has a prior action between the same parties and based on the same claim ever been filed in this court?

YES ☑ NO ☐

5. Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)

YES ☐ NO ☑

If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?

YES ☐ NO ☑

6. Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?

YES ☐ NO ☑

7. Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).

YES ☑ NO ☐

A. If yes, in which division do all of the non-governmental parties reside?

Eastern Division ☑ Central Division ☐ Western Division ☐

B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?

Eastern Division ☐ Central Division ☐ Western Division ☐

8. If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)

YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME Dominic E. Massa
ADDRESS 60 State Street, Boston MA 02109
TELEPHONE NO. 617-526-6000

JS 44 (Rev. 3/99) **CIVIL COVER SHEET**

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

NMT Medical, Inc.

(b) County of Residence of First Listed Plaintiff Suffolk
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS

AGA Medical Corp.

County of Residence of First Listed _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

(c) Attorney's (Firm Name, Address, and Telephone Number)
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
(617) 526-6000

Attorneys (If Known)
Nikolai & Mersereau, P.A.
900 Second Avenue South, #820
Minneapolis, MN 55402
(612) 339-7461

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury

PERSONAL INJURY
- ☐ 362 Personal Injury - Med. Malpractice
- ☐ 365 Personal Injury — Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 610 Agriculture
- ☐ 620 Other Food & Drug
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 630 Liquor Laws
- ☐ 640 R.R. & Truck
- ☐ 650 Airline Regs.
- ☐ 660 Occupational Safety/Health
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 810 Selective Service
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 875 Customer Challenge 12 USC 3410
- ☐ 891 Agricultural Acts
- ☐ 892 Economic Stabilization Act
- ☐ 893 Environmental Matters
- ☐ 894 Energy Allocation Act
- ☐ 895 Freedom of Information Act
- ☐ 900 Appeal of Fee Determination Under Equal Access to Justice
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 444 Welfare
- ☐ 440 Other Civil Rights

PRISONER PETITIONS
- ☐ 510 Motions to Vacate Sentence
- Habeas Corpus:
- ☐ 530 General
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 730 Labor/Mgmt.Reporting & Disclosure Act
- ☐ 740 Railway Labor Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Empl. Ret. Inc. Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN (PLACE AN "X" IN ONE BOX ONLY)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

Patent Infringement under 35 U.S.C. Sec. 271

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION DEMAND UNDER F.R.C.P. 23

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE Gertner, J. DOCKET NUMBER 98-cv-12506-NG

DATE 12/7/04 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

US005108420A

United States Patent [19]

Marks

[11] Patent Number: 5,108,420

[45] Date of Patent: Apr. 28, 1992

[54] APERTURE OCCLUSION DEVICE

[75] Inventor: Lloyd A. Marks, Bryn Mawr, Pa.

[73] Assignee: Temple University, Philadelphia, Pa.

[21] Appl. No.: 649,593

[22] Filed: Feb. 1, 1991

[51] Int. Cl.[5] A61B 17/00

[52] U.S. Cl. 606/213; 606/78; 606/151; 606/157

[58] Field of Search 606/78, 151, 157, 158, 606/215, 108, 213; 128/898, 628, 686, 843, 831

[56] References Cited

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3,874,388	4/1975	King et al. .	
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"Metals That Remember", Steven Ashley, *Popular Science*, Jan. 1988.

"The Biocompatibility of Nitinol", L. S. Castleman et al., *Biocompatibility of Clinical Implant Materials*, chap. 5, pp. 129–154.

"Nonsurgical Implantation of a Vascular Ring Prosthesis Using Thermal Shape Memory Ti/Ni Alloy (Nitinol Wire)", Yoichi Sugita et al., vol. XXXII, *Trans Am Soc Artif Intern Organs*, 1986.

"Transluminal Expandable Nitinol Coil Stent Grafting: Preliminary Report"; Charles T. Dotter, M.D. et al., *Radiology* 147: 259–260, Apr. 1983.

"A New Percutaneous Vena Cava Filter", Andrew Cragg et al., *AJR*141, 601–604, Sep. 1983.

"Transvenous Atrial Septal Defect . . . ", Sideris et al., Abstract from the American Heart Assoc. Mtg., Nov. 1988.

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"Nonsurgical Closure of PDA: Clinical Application of the Rashkind PDA Occluder System", Rashkind et al., *Circulation*, vol. 75, No. 3, Mar. 1987.

"Percutaneous Catheter Closure of the Ductus Arteriosus in Children and Young Adults", *A.J.C.* 64, Jul. 1989.

"Outpatient Closure of the Patent Ductus Arteriosus", Wessel et al., *Circulation*, No. 5, May 1988.

"Transcatheter Umbrella Closure of Congential Heart Defect", Lock et al., *Circulation*, 75, No. 3, Mar. 1987.

"Transcatheter Closure of Atrial Septal Defects", Lock et al., *Circulation*, 79, No. 5, May 1989.

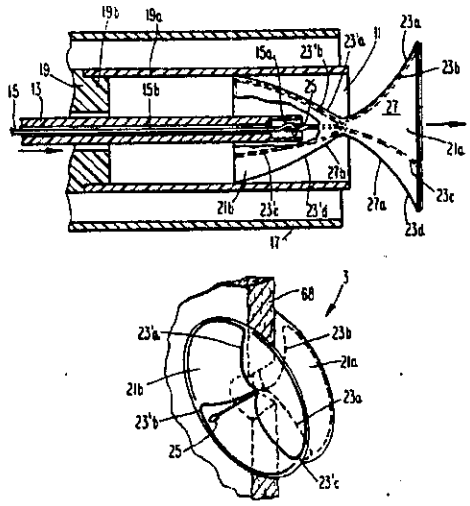
"Nonsurgical Therapy of Cardiac Disorder", Ruttenberg, *Pediatric Consult*, 5, No. 2, 1986.

Primary Examiner—Stephen C. Pellegrino
Assistant Examiner—Gary Jackson
Attorney, Agent, or Firm—Ratner & Prestia

[57] ABSTRACT

A device consisting of a wire for occluding an aperture within a body surface, such as atrial and ventricular septal defects (and the method of using such a device). The wire comprises two configurations, an elongated configuration for passage into said body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments, one on each side of said aperture. The wire also includes means (preferably a temperature-induced shape change) for changing the wire from the elongated configuration to the preprogrammed configuration in the body.

14 Claims, 3 Drawing Sheets



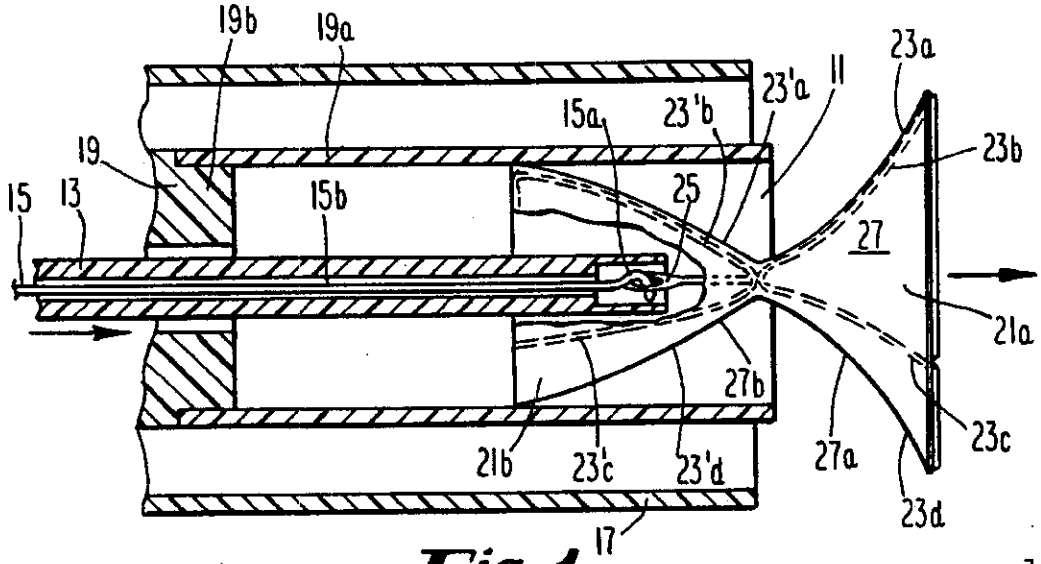


Fig. 1

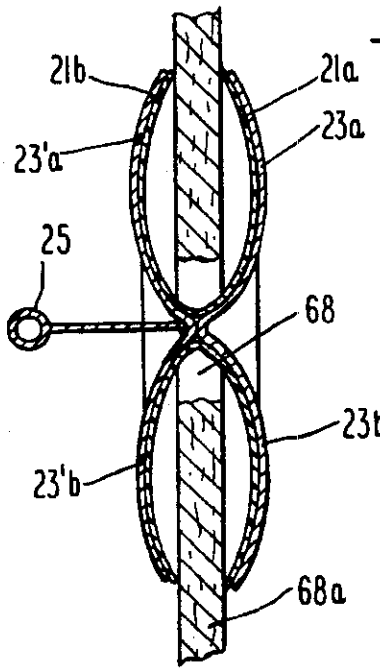


Fig. 5

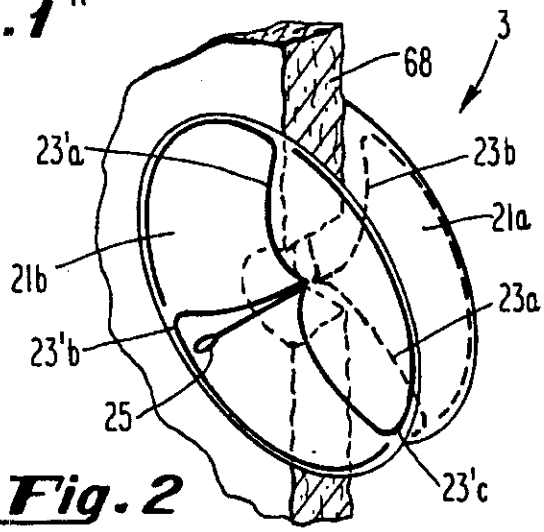


Fig. 2

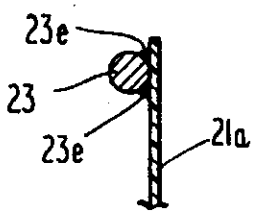


Fig. 4

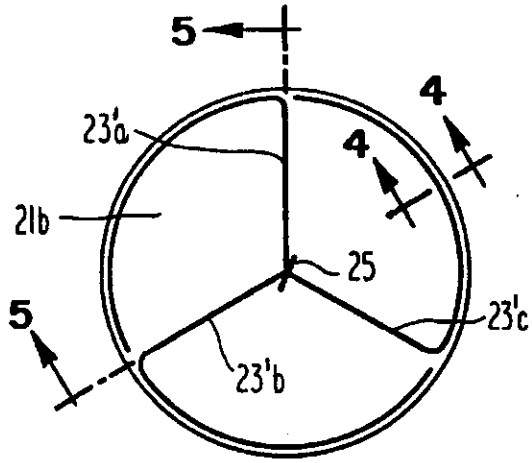


Fig. 3

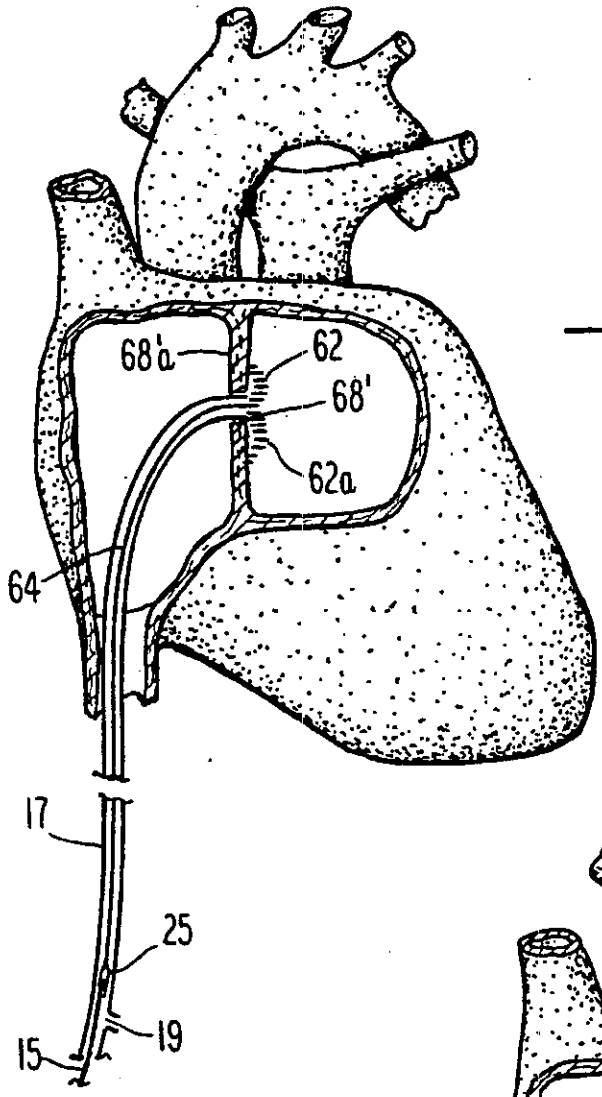


Fig. 6

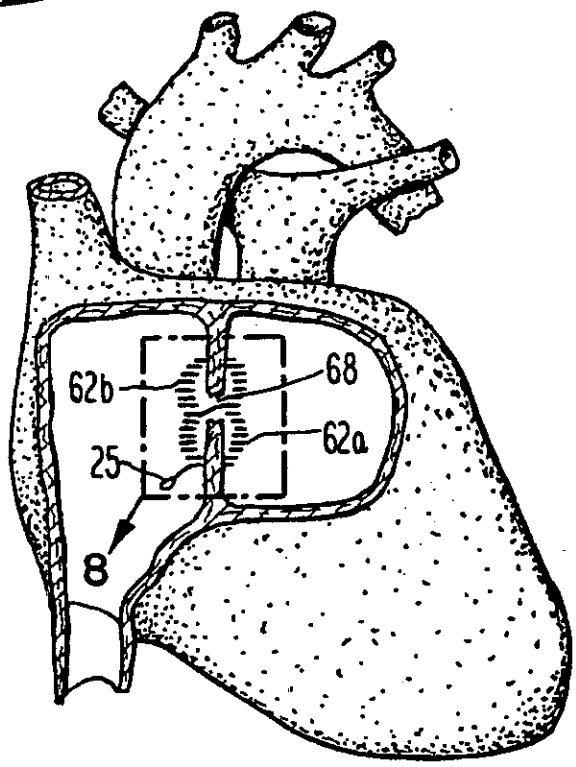


Fig. 7

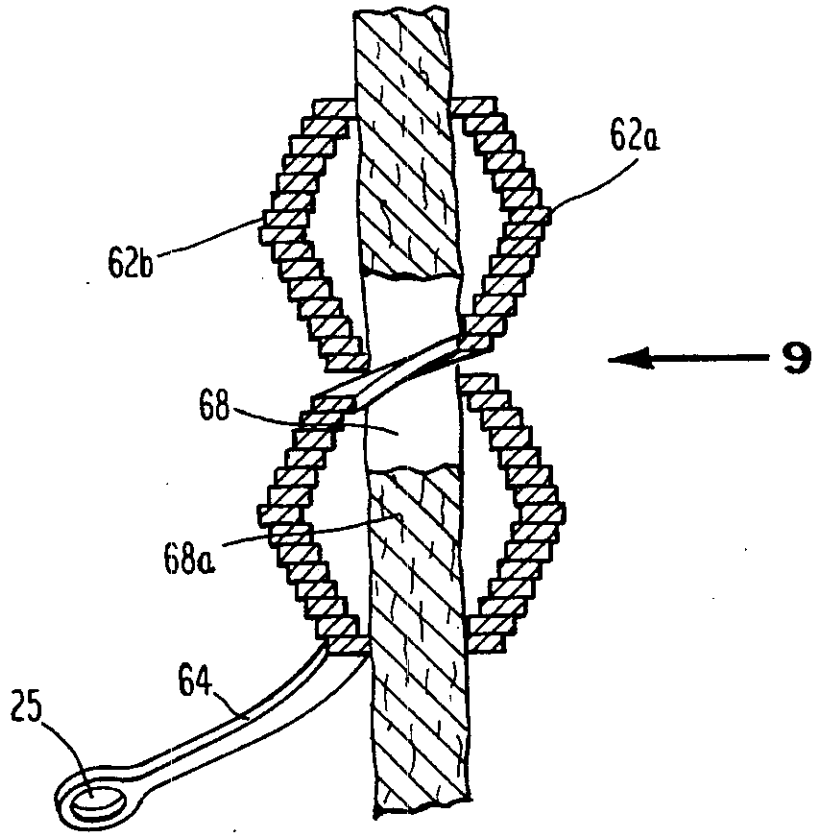


Fig. 8

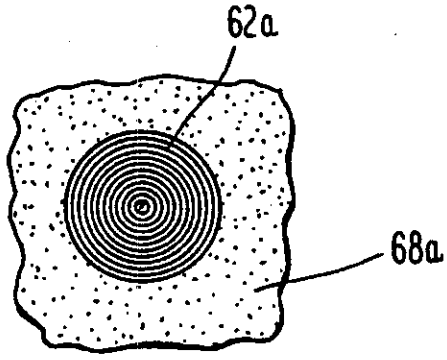


Fig. 9

APERTURE OCCLUSION DEVICE

FIELD OF THE INVENTION

The invention relates to devices and methods used to occlude (i.e. block blood flow through) an aperture within a body surface; specifically, it relates to devices and methods to occlude cardiovascular septal defects.

BACKGROUND OF THE INVENTION

It is often necessary to occlude a defect or an aperture within a body surface, such as a wall or membrane separating cavities within the body. A typical example is a congenital heart lesion called an atrial septal defect. This is a hole, between the two upper chambers of the heart, which must be closed.

King et al., U.S. Pat. No. 3,874,388, and Blake, U.S. Pat. No. 4,007,743 disclose a stainless steel apparatus for closing a shunt in the vascular system. The dual umbrella apparatus has six ribs which retain the umbrella in an open position. The King et al. apparatus has "barbs" at the ends of the ribs anchor onto the tissue surrounding the shunt. Alternatively, the barbs on the ribs of one umbrella may insert into holes on the ribs of the second umbrella, see FIG. 15A. The Blake apparatus has pivotally mounted struts which provide a flat surface to which a disk may be secured.

In "A New Percutaneous Vena Cava Filter", Cragg et al. disclose a filter composed of nitinol which when inserted into the inferior vena cava, traps emboli and clots. In the process of placing the filter, there is the threat of dislodging thrombi when the catheter or guide wire is advanced too far.

Lock et al., in *Circulation,* disclose a spring-loaded clamshell occluder of several sizes. The tension in the arms is manually controlled during delivery such that the arms of the distal umbrella, the one inserted first, are everted during placement, creating a cone.

The Rashkind occluder has two polyurethane foam disks mounted on surgical steel wire assemblies. The occluder is used to seal off the ductus arteriosus and is disclosed in *Circulation.* Vol. 75., page 583, *American Journal of Cardiology,* Vol. 64, page 218, and *Circulation,* Vol. 77, page 1068.

Devices currently used to occlude septal defects, including those indicated above, have been known to dislodge and embolize.

BRIEF DESCRIPTION OF THE INVENTION

The present invention comprises an aperture occlusion device which includes a wire having two configurations, an elongated configuration for passage through a catheter and through the aperture, and a second, preprogrammed, configuration. In the second configuration, two occlusion-forming wire segments oppose one another. These are adapted to be deployed on each side of the aperture to be occluded. A means for changing the wire from the elongated configuration to the preprogrammed configuration inside the body is further included. Typically, this may consist of a thermally responsive wire composition, the wire being preprogrammed so that at a certain temperature (body temperature for example), the wire, which is normally straight at other temperatures assumes a different ("preprogrammed") shape or configuration. Each occlusion-forming wire segment is adapted to press toward the opposing segment, thereby closing or occluding the aperture. Apertures or openings in other walls or membranes within the body or abnormally patent blood vessels may be similarly occluded.

In one embodiment, the occlusion-forming wire segments may comprise essentially flat helices, urged toward one another. In another embodiment, the wire may further include two foldable membranes, one associated with each occlusion-forming wire segment. The membranes are folded for transport through the catheter along with the wire. Upon conversion of the wire to its preprogrammed configuration, the membranes unfold onto a frame produced by the occlusion-forming wire segments, one on each side of the aperture.

Also included in the invention is a method for occluding an aperture by positioning a catheter at the distal side of the aperture and deploying a wire therethrough in an elongated configuration, (with the aid of a means for holding the wire) to the distal side of the aperture. Upon exiting the catheter, the wire converts to a preprogrammed configuration including an occlusion-forming wire segment on the distal side of the aperture. Upon continued deployment in the elongated configuration, the wire is permitted to assume the preprogrammed configuration including an opposing occlusion-forming wire segment on the proximal side of the aperture, with the two segments pressing toward one another. The wire is then disengaged from the means for holding the wire.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 is a schematic cross-sectional view, during deployment, of one embodiment of the aperture occlusion device of the claimed invention;

FIG. 2 is a perspective view of another aperture occlusion device of the present invention in a fully deployed configuration;

FIG. 3 is planar view of the device shown in FIG. 2;

FIG. 4 is an enlarged cross-sectional view, in the plane 4—4 of FIG. 3;

FIG. 5 is a cross-sectional view, in plane 5—5, of the fully deployed aperture occlusion device shown in FIG. 3;

FIG. 6 is a perspective view of a heart, partially in cross-section, schematically showing an atrial septal defect and an occlusion device of the present invention partially deployed;

FIG. 7 is similar to FIG. 6, with the occlusion device fully deployed;

FIG. 8 is an enlarged cross-sectional view of the deployed aperture occlusion device shown in FIG. 7;

FIG. 9 is a planar view of the aperture occlusion device of FIG. 8.

DETAILED DESCRIPTION OF THE INVENTION

The invention includes devices and methods for occluding apertures in body surfaces, such as walls or membranes; the devices are adapted to be passed into the body through a catheter and through the aperture. Such apertures are openings, often congenital defects, connecting two cavities of the body. Fallopian tubes may also be occluded by using the devices and methods of the claimed invention. Cardiac septal defects are the type of apertures for which the preferred embodiments of the invention are designed. For example, the devices and methods of the present invention may be used to occlude a ventricular septal defect or an unwanted

vascular communication such as a patent ductus arteriosus.

An essential part of the present invention is a wire having two configurations, an elongated configuration or folded configuration for passage into the body through a catheter and through the aperture, and a preprogrammed configuration including occlusion-forming wire segments one on each side of the aperture. This wire also includes a means for causing it to change from the elongated configuration to the preprogrammed configuration inside the body. The device may also be combined with a catheter means for introducing the wire into the body. The catheter includes means for holding the wire, such as a release wire, while it is in the catheter and before it has been stimulated to convert to the preprogrammed configuration.

Preferably the wire is composed of a shape memory retentive material, such as nitinol, which causes the wire to change configurations, in response to a temperature change and which enables the wire to be activated at body temperature (having previously been at a different temperature) to assume a preprogrammed configuration. Spring steel may also serve this purpose. Furthermore, the wire must be biocompatible, and may be coated with Teflon, fibrin or endothelial cells, for example.

The occlusion forming wires may be associated with a foldable membrane, either by being embedded in the membrane or secured (by glue, stitches, staples or the like) to the surface thereof. In this embodiment, the membrane is transportable through a catheter in a folded configuration along with the wire. The occlusion-forming wires are adapted, upon converting to preprogrammed configuration, to unfold the membranes and to form a frame to support the membranes as domed or umbrella-shaped members on each side of the aperture. In another embodiment, the occlusion-forming wire is not attached to a membrane, and forms coiled helices, one on either side of the defect and urged toward each other.

Referring to FIG. 1, there is shown a partially deployed stage of one aperture occlusion device. As would be used for the occlusion of a septal defect, sheath **17** (a large catheter), after entering the body in a conventional manner, such as through a femoral vein, enters the heart via the inferior vena cava and is positioned on the distal side of an atrial septal defect in the body of the left atrium.

Release wire **15**, including shaft **15***b* and knuckle **15***a*, device engaging catheter **13** and aperture occlusion device **27**, all disposed within deployment catheter **19**, are prepared as a unit prior to deployment through sheath **17** and introduced into the body either along with or later through sheath **17**.

Aperture occlusion device **27** is composed of two biocompatible membranes **21***a* and **21***b*, each comprised of a thin polyurethane membrane film, for example. Preprogrammed shape memory retentive, wire ribs **23** and **23'** are secured (and may be threaded, sewn or sandwiched) to each biocompatible membrane **21***a* and **21***b*. Eye **25**, attached to wire ribs **23** and **23'**, extends from the center of aperture occlusion device **27** and engages knuckle **15***a* of release wire **15**. One half of aperture occlusion device **27***b* is seen in the folded state; upon release from deployment catheter **19** and contact with body temperature, the membrane expands between the ribs, as shown by device half **27***a* with associated ribs **23**. In FIG. **1**, four wire ribs, **23***a–d* and **23'***a–d*, on each half of device **27**, unfold, i.e. are converted from their elongated configuration to a second preprogrammed configuration, such as by a thermally stimulated shape change to a preprogrammed configuration, which urges the wire ribs outwardly, to expand and release. For this purpose, ribs **23***a–d* and **23'***a–d* are composed of a thermally responsive shape, shape memory retentive material, such as nitinol.

For transport to the site of deployment, the unit including release wire **15**, device engaging catheter **13** and aperture occlusion device **27** are channeled into pod **11** of deployment catheter **19**. Deployment catheter **19** includes an inner plastic portion **19***b* integrally connected to outer metal portion **19***a*. Release wire **15**, device engaging catheter **13** and aperture occlusion device **27** are retained together and folded in deployment catheter **19**. In practice, device **27** may be deployed without the use of deployment catheter **19**, so long as sheath **17** is in a cold environment thus prohibiting device **27** from forming the preprogrammed shape.

In use, the assembly including release wire **15**, device engaging catheter **13**, aperture occlusion device **27** and deployment catheter **19** are passed through sheath **17** until the distal half of device **27** is disposed on the distal side of the septal defect (i.e. "aperture") to be occluded. Device engaging catheter **13**, release wire **15**, and aperture occlusion device **27** are maintained in place on the distal side of the defect while sheath **17** is retracted back through the defect to the proximal side thereof. Device engaging catheter **13** and release wire **15** are advanced freeing **27***a* to expand to preprogrammed shape. This enables a thermally stimulated shape change to the preprogrammed deployed configuration of ribs **23***a–d*. One-half of aperture occlusion device, **27***a*, is thus deployed on the distal side of the septal defect.

Coincident with the pull-back movement of deployment catheter **19** either in the preceding step or in the following step, sheath **17** is also retracted away from the aperture to be occluded.

Aperture occlusion device **27** is then pulled taut against the defect such that four wire ribs **23***a–d* expand and contact the heart tissue around the defect. Optionally, sheath **17** is then pulled back further away from the proximal side of the defect (if that had not been done earlier), and deployment catheter **19** is retracted leaving device engaging catheter **13**, release wire **15**, and aperture occlusion device **27** in place and thus exposing aperture occlusion device half **27***b* on the proximal side of the defect, at which point the second half **27***b* of device **27** is deployed.

Once aperture occlusion device **27** is fully deployed, as seen in FIGS. **2–5**, knuckle **15***a* is disengaged from eye **25** of aperture occlusion device **27**, by retracting catheter **13** slightly from eye **25**. The assembly including deployment catheter **19**, device engaging catheter **13** and release wire **15** are then retracted from sheath **17**. Finally, sheath **17** is also retracted from the body.

FIG. **2** depicts a perspective view of an aperture occlusion device, with **3** ribs, like that seen in FIG. **1**, but fully deployed to occlude a defect or aperture **68** in wall **68***a*. Membranes **21***a* and **21***b* are supported by wire ribs **23***a–c* and **23'***a–c* respectively, which urge the membranes toward each other and connect the membranes with eye **25**.

As seen in FIG. **3**, membrane **21***a* is attached to three wire ribs **23***a, b* and *c* extending circumferentially then curving and radially extending to the center of membrane **21***a*. Ribs **23***a–c* attach at the center of membrane

21*a* and connect the pair to each other and to eye 25 which attaches to a release wire, not shown. Ribs 23*a–c*, upon thermal triggering of the memory retentive properties of the rib material (preferably nitinol), support and maintain the shape of membrane 21*a*. Membrane 21*b* is similarly retained by ribs 23'*a–c*.

FIG. 4 is a cross-section through plane 4—4 of FIG. 3. As depicted therein, membrane 21*a* is secured to rib 23*a* by glue 23*e*. Stitches, staples or the like may also be used to affix membrane 21*a* to rib 23*a*. Other configurations of ribs 23*a, b, c* may also be used.

FIG. 5 illustrates a cross-section along plane 5—5 of the aperture occlusion device of FIG. 3. Membranes 21*a* and 21*b* occlude aperture 68 in wall 68*a*, and are supported by wire ribs, 23*a, b* and 23'*a, b*, which urge the membranes toward each other and connect the membranes with eye 25.

FIG. 6 depicts septal defect 68' with a double helix occlusion device 62 partially deployed. Device 62 is introduced as a straight wire 64 through the assembly including, device engaging catheter 13 (like that shown in FIG. 1, but not shown in FIG. 6 due to limited space available), release wire 15 and sheath 17. Sheath 17 is diametrically larger than device engaging catheter 13 to allow passage of device engaging catheter 13 therethrough. As with the assembly shown in and described with respect to FIG. 1, the assembly of release wire 15, device engaging catheter 13, wire 64 and sheath 17 are introduced through a large vein to and through the defect to be occluded. Sheath 17 optionally may be stopped short of defect 68' and may be withdrawn with device engaging catheter 13, as described, or independently of catheter 13.

Helix 62*a* is formed on the distal side of defect 68', preferably by the coiling of wire 64, nitinol for example, in response to a temperature change, upon body temperature contact or by retraction of spring steel into its "relaxed" (preprogrammed) configuration. A plurality of coils of progressively smaller diameter are formed, finally contacting the periphery of atrial wall 68*a*' surrounding defect 68' on the distal side thereof; each such coil of wire 64 contacts the previously formed coil above and below defect 68', such that helix 62*a* is deployed from the outside in, (relative to defect 68), until helix 62*a* is formed (as seen in FIG. 6).

The aperture occlusion device of FIG. 6 after deployment into the left atrium is seen in FIG. 9. The concentric circles are the result of the coiling of wire 64 (in this case from a very small starting circumference out) and also contacting the previously formed coil above and below defect 68', this time on the proximal side thereof.

After deploying helix 62*a* on the distal side of defect 68, sheath 17, device engaging catheter 13, release wire 15, and wire 64 are withdrawn equally and together to bring helix 62*a* into firm contact with the septal surface. As tension is maintained on wire 64 via release wire 15, sheath 17 is withdrawn over wire 64 and release wire 15, thereby exposing a length of wire 64 on the proximal side of the defect. Tension on wire 64 is then slowly reduced by advancing release wire 15 and sheath 17 equally and together. Wire 64 begins coiling at or near septal surface below defect 68. By progressively reducing tension on wire 64 (by repetitively withdrawing sheath 17 over release wire 15 and advancing sheath 17 and release wire 15 equally and together), successive coils are formed, each moving outward beyond the previously formed coil. Thus, helix 62*b* is formed from the inside out, until helix 62*b* is fully deployed as seen in FIGS. 7 and 8. Eye 25 is then disengaged from the release wire 15 (not shown), and the remaining apparatus is removed from the body as described with respect to FIG. 1.

In those embodiments dependent upon a thermally responsive change (such as with nitinol) as the means for effecting device deployment, it is desirable prior to deployment to continuously infuse a biocompatible fluid (such as normal saline) which is substantially below body temperature (for example at room temperature) through side port 19 of sheath 17 to maintain a thermal environment within sheath 17, that is below the transition temperature of the thermally responsive wire 64. This assures that wire 64 will not assume its programmed shape until it exits sheath 17.

Furthermore, the programmed deployed configuration of the double helix coil (in the embodiment of FIGS. 6–9) may preferably include shaping to urge the outermost coils of helices 62*a* and 62*b* inward toward the septal surface (and one another) to provide an increased frictional force between the helices and their respective septal surfaces.

By way of general description of the method of this invention, the device of the present invention may be used in a method of occluding an aperture within a body surface. A catheter, which can accommodate a wire in an elongated or folded configuration (optionally with an associated membrane), is introduced through a body member such as a femoral vein, deployed, for example, into the heart through the inferior vena cava and manipulated into position on the distal side of the aperture where the wire assumes its preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the distal side of the septal defect. Withdrawing the catheter partially over the wire allows a substantial length of the wire to be exposed on the near side of the defect. Upon further deployment, the wire assumes a preprogrammed configuration including an occlusion-forming wire segment urged toward the aperture on the proximal side of the aperture. The wire is then disengaged from the means for holding it.

The device and method of this invention are believed to be particularly well adapted to occlude both atrial and ventricular septal defects, as well as other cardiovascular openings, such as a patent ductus arteriosus. The device (modified for tubal rather than aperture occlusion) is also well suited for use in occluding fallopian tubes.

In the embodiments disclosed, the finished structure comprises two connected occlusion-forming wire segments, disposed on opposite sides of an aperture, each formed of a wire resulting in helices, or domed members (with membranes attached to a wire frame), urged toward one another.

While this invention has been disclosed with reference to specific embodiments, it is apparent that other embodiments and equivalent variations of this invention may be devised by those skilled in the art without departing from the true spirit and scope of this invention. The appended claims are intended to be construed to include all such embodiments and equivalent variations.

What is claimed is:

1. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said cathe-

ter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture urged toward one another and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, said means being a temperature responsive material of construction of said wire, by which said wire is activated at body temperature, to assume said preprogrammed configuration.

2. A device of claim 1 wherein said wire is combined with a catheter means for introducing said wire into said body, said catheter means also includes means for holding said wire, while it is in said catheter, at a temperature at which said wire does not tend to assume said preprogrammed configuration.

3. A device of claim 1 wherein said occlusion-forming segments each comprise helical coils urged toward one another.

4. A device of claim 1 wherein said wire further includes two foldable membranes, one associated with said first occlusion-forming wire segment and the other associated with said second occlusion-forming wire segment, said membranes in folded configuration being transportable through a catheter along with said wire, said wire adapted upon converting from said elongated configuration to said preprogrammed configuration to unfold said membranes and to form a frame supporting said membranes as essentially planar members, one disposed on each side of said aperture, and urged toward one another, wherein said means for causing a change in configuration is a thermally responsive material of construction.

5. A device according to claim 4 wherein said wire is secured to said membranes of said occlusion-forming wire segments.

6. A device according to claim 1, wherein said wire consists of nitinol.

7. A device according to claim 1, wherein said wire is biocompatible.

8. A device according to claim 1, wherein said wire is coated to enhance biocompatibility.

9. A device adapted to occlude an aperture within a body surface, and adapted to be passed into said body, through a catheter and through said aperture, said device comprising a wire having two configurations, an elongated configuration for passage through said catheter and through said aperture, and a preprogrammed configuration which includes occlusion-forming wire segments one on each side of said aperture, and means for causing said wire to change from said elongated configuration to said preprogrammed configuration inside said body, wherein said occlusion forming segments each comprise helical coils urged toward one another.

10. A device according to claim 9, wherein said wire consists of spring steel.

11. A method for occluding an aperture within a body surface by positioning the end of a catheter at the distal side of the aperture, deploying a wire of temperature responsive material of construction in an elongated configuration through said catheter to the distal side of said aperture with the aid of a means for holding said wire, permitting the wire exposed thereby to assume a preprogrammed configuration, including an occlusion-forming wire segment on the distal side of said aperture, and urged toward said aperture, withdrawing the end of said catheter through said aperture and deploying an additional length of said wire in an elongated configuration to be exposed on the proximal side of said aperture, whereupon said continued deployment, said wire is permitted to assume a preprogrammed configuration, including an opposing occlusion-forming wire segment urged toward said aperture on the proximal side of the aperture, and disengaging the wire from the means for holding said wire.

12. A method as recited in claim 11, wherein said defect is a atrial septal defect.

13. A method as recited in claim 11, wherein said defect is a ventricular septal defect.

14. A method as recited in claim 11, wherein said defect is a patent ductus arteriosus.

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